

MARKED UP VERSION SHOWING CHANGES MADE:

1. (Amended). An isolated HIV-1 Group O env polypeptide having at least 80% identity with an amino acid sequence [consisting essentially of] of Figure 1 (SEQ ID NO:61).

2. (Amended). An isolated HIV-1 Group O env polypeptide [comprising] having an immunoreactive portion of a polypeptide according to claim 1.

REMARKS

Reconsideration and allowance of the above-referenced application are respectfully requested.

Claims 1 and 2 have been amended. Support for the amendment to claim 1 can be found on page 9, lines 35-36. Claim 2 has been amended so that its scope is commensurate with that of claim 1. No new matter has been added as a result of these amendments.

Rejection of Claims 1 and 2 under 35 U.S.C. Section 112,  
Second Paragraph

Claims 1 and 2 are rejected under 35 U.S.C. Section 112, second paragraph, as being indefinite. With respect to claim 1, the Examiner states that the term "consisting essentially of" is defined in the specification on page 9, lines 33-35 to include variant polypeptides whose structural and functional characteristics remain substantially the same. The Examiner states that it is not clear at all what characteristics can change and still be considered to be "substantially the same". Therefore, the metes and bounds of the claimed protein are indefinite. Claim 2 is rejected because it depends upon claim 1. Applicants respectfully traverse this rejection.

Claims 1 and 2 have been amended. More specifically, claim 1 has been amended to recite that the isolated HIV-1 Group O env polypeptide has at least 80% identity with an amino acid sequence of Figure 1 (SEQ ID NO:61). Applicants submit that this amendment removes the indefiniteness issue raised by the Examiner.

Claim 2 has been amended so that its scope is commensurate with that of claim 1.

Thereupon, in view of the aforementioned amendments and arguments, Applicants submit that this rejection should be withdrawn.

Rejection of Claims 1 and 2 under 35 U.S.C. Section 112,  
First Paragraph

Claim 1 and 2 are rejected under 35 U.S.C. Section 112, first paragraph. Specifically, the Examiner states that claim 1 is drawn to Group O env proteins which vary from SEQ ID NO:61 as long as they are in some manner "substantially the same" in structural and functional characteristics. According to the Examiner, this claim encompasses Group O env proteins that have not yet been discovered, and the specification provides no basis to predict the structural and functional characteristics of the as-yet undiscovered Group O env proteins. The Examiner also points out that claim 2 is even more broadly drawn. Applicants respectfully traverse this rejection.

As discussed previously, claims 1 and 2 have been amended. Specifically, claim 1 has been amended to recite that the isolated HIV-1 Group O env polypeptide has at least 80% identity with an amino acid sequence of Figure 1 (SEQ ID NO:61). As shown in Example 15 (pages 54-57 of the specification), polypeptides derived from SEQ ID NO:61 were used in immunoassays, these polypeptides significantly improved the sensitivity of such immunoassays for detecting HIV-1 Group O-infected sera.

Claim 2 has been amended so that its scope is commensurate with that of claim 1.

Thereupon, in view of the aforementioned amendments and arguments, Applicants submit that this rejection should be withdrawn.

#### Claim Objections

Claim 2 is objected to under 37 C.F.R. Section 1.75(c) as being in improper dependent form for failing to further limit the subject matter of the previous claim. In response to this rejection, Applicants have amended claim 2. In view of this amendment, Applicants submit that this rejection has now been rendered moot and should be withdrawn.

#### Rejection of Claims 1-2 Under 35 U.S.C. Section 103(a)

Claims 1 and 2 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over Delaporte et al. (AIDS, 1996, vol. pages 903-910). According to the Examiner, Delaporte teaches a DNA sequence (Sequence deposited in EMBL X96526, page 905, column 2, second paragraph from the bottom) that encodes an HIV-1 Group O env polypeptide that is 83.5% identical to SEQ ID NO:61. Therefore, according to the Examiner, this reference explicitly suggests an isolated HIV-1 Group O env polypeptide that meets the bounds of the presently claimed invention. Applicants respectfully traverse this rejection.

Delaporte et al. does not disclose any nucleotide or amino acid sequence for the HIV-1 Group O env polypeptide. Rather all Delaporte et al. disclose is that "[T]he nucleotide sequence data were deposited in the European Molecular Biology Laboratory, GenBank and DNA Data

Bank of Japan Nucleotide Sequence Databases under the following accession numbers. (X90912 to X90924 and X96526)."

The Examiner has failed to provide any information regarding the public availability of these accessions. Therefore, because Delaporte et al. fail to specifically teach any nucleotide or amino acid sequences, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness.

Additionally, Applicants herewith enclose a 37 C.F.R. Section 1.132 Declaration of Dr. John Hackett, Jr., who is one of the inventors of the above-identified application. As the Examiner is aware, Delaporte et al. was published in 1996. As discussed in his declaration, Dr. Hackett tried to verify the exact publication of Delaporte et al. All Dr. Hackett could learn was that this document was published in July 1996.

As discussed above on page 905, Delaporte et al. refer to Accession Number X96526. As the Declaration further describes, Dr. Hackett conducted a search to determine the actual sequence of this Accession. Dr. Hackett located Accession X96526 in the EMBL database. Once Dr. Hackett obtained the sequence he conducted an inquiry to determine when the sequence for this Accession became publicly available. As a result of his inquiry, Dr. Hackett learned that Accession X96526 became publicly available on August 28, 1996. If the Examiner has information to the contrary on either the publication date of Delaporte et al. or the public availability of Accession X96526, Applicants would appreciate receiving this information.

Also attached is a 37 C.F.R. Section 1.131 Declaration of Dr. Sushil G. Devare, who is also one of the inventors of the above-identified application. As discussed in Dr. Devare's declaration, the present invention pre-dates the date that Accession X96526 became publicly available. Therefore, Applicants further submit that Accession Number X96526 as well as Delaporte et al. are not prior art and that this rejection should be withdrawn.

Conclusion

In view of the aforementioned amendments and arguments, Applicants submit that the claims 1-2 are in condition for allowance.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 01-0025.



23492

ABBOTT LABORATORIES  
Telephone: (847) 938-3137  
Facsimile: (847) 938-2623

Respectfully submitted,  
J. Hackett Jr. et al.

Lisa V. Mueller  
Registration No. 38,978  
for Dianne Casuto  
Registration No. 40,943  
Attorney for Applicants